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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,506	04/22/2004	Marvin John Cervantes	P1482 US (2650/81)	7331

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MEDTRONIC VASCULAR, INC.
3576 Unocal Place
Santa, Rosa, CA 95403

EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,506	Applicant(s) CERVANTES, MARVIN JOHN	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/28/09, 4/3/08 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims filed 4/28/09.

Drawings

The drawings were received on 4/3/08 and 4/28/09. These drawings are not accepted, as the location of the o-ring is not supported in the originally filed claims.

Specification

The amendment filed 4/28/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the o-ring being at the distal end of the Y-arm.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 1 refers to a stent deployment assembly as “the stent assembly” and as “the stent deployment assembly”. The Examiner suggests that all occurrences of “the stent deployment assembly” be changed to maintain consistency and clarity.

Claim Rejections - 35 USC § 112

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not teach the o-ring being disposed in relation to the port, specifically “the o-ring disposed at a distal end of the port”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain et al. (U.S. Patent No. 5,534,007) and further in view of Fischell et al. (U.S. Patent No. 6,20,521).

Claim 1:

St. Germain teaches a system for treating a vascular condition, comprising: a catheter (60); a stent deployment assembly (155) coupled to the catheter (15); a stent framework (30), a protective sleeve (40) removably covering the stent deployment

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assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter at a distal end of the sleeve and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly (Fig. 8, 40 encircles 30), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open (Fig. 6), and a port to a vessel (portion between 55 and 60), the port including an o-ring having an o-ring inner diameter (60 acts as an o-ring), the o-ring disposed at a distal end of the port (Fig. 6) wherein a proximal portion of the sleeve (40) is positioned proximal to the o-ring (Fig. 8) and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 8), wherein the o-ring inner diameter is greater than the diameter of the stent deployment assembly (155, Fig. 6) and less than the diameter of the distal end of the sleeve (40, Fig. 6), wherein the protective sleeve is sized to be removed from covering the stent framework upon contact of the distal end of the protective sleeve with a proximal side of the o-ring as the stent enters the vessel (Figs. 2-3).

St. Germain does not specify a drug coating disposed on at least a portion of the stent framework, however Fischell teaches a drug coating disposed on at least a portion of the stent framework (col. 5, ll. 32-34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a coating of Fischell with the stent of St. Germain, as using a coating on the stent has been proven successful in the art for drug delivery and aids in biocompatibility.

Claim 5:

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St. Germain teaches the sleeve comprises a polymer (col. 3, ll. 40)

Claim 6:

St. Germain and Fischell teach the claimed invention but do not specify the sleeve comprising a material that dissolves while in a vasculature. It would have been obvious to one of ordinary skill in the art to use a biodegradable material as it is well known in the art to use a biodegradable material for a stent sleeve, as this omits a surgery to remove the sleeve later on.

Claims 7 and 8:

St. Germain teaches the claimed invention but does not teach a lubricious coating on at least a portion of a surface of the sleeve, however Fischell teaches a lubricious coating on at least a portion of a surface of the sleeve (col. 2, ll. 54), the examiner interprets the coating to be a lubricious film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the coating of Fischell with the device of St. Germain, as this aids in a smoother delivery of the device and helps to protect the stent.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain et al. (U.S. Patent No. 5,534,007) and Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above, and further in view of Roberts et al. (U.S. Patent No. 5,984,964).

St. Germaine and Fischell teach the claimed invention above, however does not specify dimensions of the sleeve, however Roberts teaches the sleeve has a distal inner

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diameter of substantially .071 centimeters, a distal outer diameter of substantially .0825 centimeters (col. 4, ll. 52-59), a medial inner diameter (L7) of .045 centimeters, and a medial outer diameter of .055 centimeters (col. 4, ll. 59-63).

It would have been obvious to one of ordinary skill in the art to have the dimensions of Roberts as these dimensions are appropriate for use in the vasculature. Also, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

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/Julian W. Woo/

Primary Examiner, Art Unit 3773